

Remarks

Applicants have reviewed the Office Action mailed April 28, 2011. Claims 2-8, 10-12, 14, and 33-43 are pending. Claims 2, 4, 5, 8, 10-12, 33, and 35-43 are amended. Applicants submit that no new matter has been entered as a result of the amendments. Applicants respectfully submit the following remarks.

Drawings Objections

In the Office Action, the Examiner objected to the drawings based on the label of the y-axis in Figure 22. Applicants thank the Examiner for noticing the informality, which is corrected by the amended figure in the attached replacement sheet. Accordingly, Applicants respectfully request that the objection to the drawings be withdrawn.

Claim Objections

Applicants thank the Examiner for pointing out the informalities which are now corrected by the above amendments to claims 4, 5, and 42. Accordingly, Applicants respectfully request that the claim objections be withdrawn.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 11, 35, and 40-41 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Examiner stated that it was unclear whether the language “may be used” was positively claimed. The Examiner also rejected claim 40 on the basis that there was insufficient antecedent basis for the limitation “the detection cluster.”

Applicants have amended claims 11, 35, and 41 to address the Examiner’s rejections by indicating that the lowest relative severity score is useful for minimizing a probability of missing clinical events and by providing proper antecedent basis for the detection cluster in amended claim 40. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of claims 11, 35, and 40-41.

Claim Rejections Under 35 U.S.C. § 102

Claims 2-8, 10-12, and 33-43 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by WIPO International Publication (WO 00/10455 A1) to Echauz et al. ("Echauz"). Applicants respectfully traverse the rejection because Echauz does not disclose all the limitations of the claims. To show anticipation under 35 U.S.C. § 102, an examiner "must show that each element of the Claim in issue is found, either expressly or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied a single prior art device or practice."¹

Applicants respectfully submit that the claims as previously presented are not anticipated by Echauz, but have amended the claims to further distinguish from Echauz solely for the purpose of securing allowed claims at an earlier date. No prejudice or disclaimer should be inferred, and Applicants reserve the right to prosecute the originally filed and previously presented claims in the future. To the extent the current rejections may apply to the amended claims, Applicants respectfully traverse the rejections and submit that Echauz does not disclose or otherwise suggest all of the limitations of the currently presented claims. In addition, Applicants respectfully submit that there is no convincing line of reasoning for a finding of obviousness in place of the undisclosed limitations.

Independent Claims

Amended independent claim 2 provides a computer-implemented method for scoring a severity of a neurological event that includes

- (a) determining using a processor that one or more sensed neurological signals represent a plurality of neurological events;
- (b) identifying using a processor at least one feature of each of the plurality of neurological events, wherein the plurality of neurological events are selected from the group consisting of a detection cluster event and a reported event;
- (c) computing using a processor a relative severity score for each of the plurality of neurological events using the at least one feature; and

¹ *Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed. Cir. 1992). See also MPEP § 2131.

- (d) ranking using a processor the plurality of neurological events by severity using the relative severity scores.

Applicants respectfully traverse the rejection over Echauz to the extent it may apply to amended claim 2 because Echauz at least does not disclose or suggest the limitations in steps (c) and (d) of amended claim 2.

In rejecting claim 2, the Examiner stated that a prodrome in Echauz is the same as a neurological event as provided in claim 2 and thus Echauz's "prodrome detection" discloses step (a) of claim 2.² The Examiner also equated Echauz's "probability of seizure occurrence" with the relative severity score in step (c) of claim 2.³ Applicants respectfully disagree with this interpretation and application of Echauz. Generating a probability that a seizure will occur in the future is not the same as computing a relative severity score of a neurological event that has already been determined to have occurred. In addition, Applicants note that amended claim 2 requires computing a relative severity score for each of a plurality of neurological events. The relative severity score of claim 2 is associated with or assigned to a particular neurological event, and indicates the severity of the particular neurological event. However, Echauz does not disclose computing a seizure probability for each of a plurality of prodromes that have already occurred (i.e., neurological events according to the Examiner). Instead, while Echauz's seizure probabilities may be generated using past information, the seizure probabilities themselves are associated with a number of time horizons in the future.⁴ Further, it is unclear why one skilled in the art would consider modifying Echauz to provide the limitations of claim 2 since there is no need to determine the probability of the occurrence of a prodrome that has occurred in the past.

Applicants also submit that Echauz does not disclose using a processor to rank a plurality of neurological events by severity using relative severity scores. In the Office Action, the Examiner stated that "Echauz further teaches that 'higher actual probabilities occur when several pre-ictal prodromes are detected in a 3 hour period'" and interpreted this as disclosing the claimed ranking.⁵ Applicants respectfully disagree with this characterization of Echauz. The pertinent portion of Echauz, p. 39, to which the Examiner referred is reproduced below:

² Office Action, p. 4.

³ Office Action, p. 5, lines 14-15.

⁴ Echauz, p. 39, line 7; p. 26, lines 13-24.

⁵ Office Action, p. 5.

WO 00/10455

PCT/US99/19387

39

complementary historical feature vector is generated that contain counts of the occurrence of a pre-ictal prodrome in the last "n" time windows (by template matching or frequency/ time domain characteristics), counts of drops in fractal dimension for the last "n" windows below a certain threshold, and features of accumulated energy profiles including the last value and number of slope changes. Both of these feature vectors are fed into the series of wavelet neural networks and probabilities of seizure occurrence for each time horizon are continuously calculated. Higher actual probabilities occur when several pre-ictal prodromes are detected in a 3 hour period, when the trend in accumulated energy deviates by a certain threshold amount from baseline tracings, or when the WNNs calculate increased probability of a seizure based on feature behavior that is not generally visible to the naked eye.

As can be seen in context, Echauz only provides a general statement (presumably based on undisclosed observations) that "higher actual probabilities occur" in a number of situations, including when several pre-ictal prodromes are detected in a 3 hour period. This is not a "ranking using a processor" as provided in claim 2. In addition, Echauz does not disclose or even contemplate the usefulness of ranking prodromes (neurological events according to the Examiner's interpretation) relative to each other using a computed relative severity score of each of the prodromes. Instead, Echauz is interested in generating probabilities of seizures along a future time horizon.

Accordingly, Applicants respectfully submit that at least for these reasons, Echauz fails to teach, suggest, or imply all of the limitations of independent claim 2. In addition, Applicants respectfully submit that there is no convincing line of reasoning for a finding of obviousness in place of the undisclosed limitations. Independent claims 33 and 38 include one or more limitations similar to those in independent claim 2, and thus are believed to be patentable for at least one or more of the reasons presented above. In particular, Applicants note that claim 33 provides for computing using a processor a relative severity score for each of a plurality of detection clusters and ranking using a processor the detection clusters using the relative severity scores. Claim 38 provides for computing using a processor a relative severity score for each of a

plurality of neurological events. Accordingly, Applicants submit that independent claims 2, 33, and 38 are patentable over Echauz and respectfully request that the rejection be withdrawn.

Dependent Claims

Claims 3-8, 10-12, 14 depend from independent claim 1, claims 34-37 depend from independent claim 33, and claims 39-42 depend from independent claim 38, and thus are all believed to be patentable for at least the reasons given above with respect to the independent claims, as well as based upon additional patentable features and elements claimed in the dependent claims but not explicitly discussed above.

As just one example, Applicants note claim 8 depending from claim 1, which has been amended to indicate that the neurological events are seizures. While Applicants appreciate the Examiner's comments regarding claim 8, Applicants respectfully disagree at least because Echauz does not disclose the use of an extent of electrographic spread as provided in claim 8. In the Office Action, the Examiner noted that Echauz discloses that prodromes "increase in their frequency of occurrence, their amplitude or their duration as the seizure approaches"⁶ and interpreted this to mean that computing a seizure probability in Echauz relates duration (i.e., prodrome duration according to the Examiner), intensity (i.e., prodrome amplitude according to the Examiner), and extent of electrographic spread (i.e., pre-ictal EEG pattern according to the Examiner). However, while Echauz states that pre-ictal prodromes are specific pre-ictal patterns which occur on the EEG,⁷ this in no way discloses or suggests an "extent of electrographic spread" as provided in claim 8.

As provided in Applicants' originally-filed application, an "extent of electrographic spread" refers to a spatial distribution across a patient's brain, not merely a two-dimensional EEG pattern. For example, electrographic spread can be determined based on identified channels that are "involved" in a seizure.⁸ In addition, Figure 22 and the corresponding description in the originally-filed application provide an example in which waveforms 2257 and 2259 correspond to adjacent electrodes, and "thus the extent of an electrographic spread is two

⁶ Office Action, p. 7; see Echauz, p. 37, lines 21-23.

⁷ Echauz, p. 37, line 20.

⁸ Original Application, pars. [104], [189].

electrodes.”⁹ Further an embodiment may visually indicate the electrographic spread by distinguishing an electrode corresponding to a waveform that is “involved” in a seizure.¹⁰ Accordingly, Applicants submit that Echauz’s generation of seizure probabilities (i.e., the computed severity score according to the Examiner) does not involve electrographic spread, as properly construed in light of the specification. Accordingly, Applicants respectfully submit that claim 8 is also patentable for at least the additional reasons presented above and respectfully request reconsideration and withdrawal of the present rejection.

Claim Rejections Under 35 U.S.C. § 103

Claim 14 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Echauz and further in view of U.S. Patent 6,463,328 to John (“John”). Applicants respectfully traverse the rejection. Claim 14 depends from independent claim 2, and thus is believed to be patentable for at least the reasons presented above with respect to claim 2. Accordingly, Applicants respectfully request the Examiner withdraw the rejection.

⁹ Original Application, par. [125].

¹⁰ Original Application, par. [126].

Conclusion

Applicants submit that this application is in condition for allowance for at least the reasons presented above. Favorable consideration and prompt allowance of the application are respectfully requested. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 06-1910. The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

/Michael J. Feller/

Michael J. Feller
Registration No. 59,296

Dated: October 28, 2011

Customer No. 81390
FREDRIKSON & BYRON, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402-1425 USA
Telephone: (612) 492-7000
Facsimile: (612) 492-7077

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 06-1910.

4920126